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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,418	01/23/2004	Jannis G. Stavrianopoulos	Enz-61(D11)	8199

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ENZO BIOCHEM, INC.
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EXAMINER

RILEY, JEZIA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,418	STAVRIANOPOULOS ET AL.	
	Examiner	Art Unit	
	Jezia Riley	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 287-305 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 287-292,294 and 297-305 is/are rejected.
- 7) ☒ Claim(s) 293,295 and 296 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 297-305 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 295 shows a structure of a chemiluminescent reagent comprising an aromatic moiety having R and R' substituents. However it is unclear if the R substituent is attached to the ring or if R and R' are linked and form only one substituent attached to the ring.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 287-292, 294 are rejected under 35 U.S.C. 102(b) as being anticipated by Bronstein et al. (5,800,999).

Bronstein et al. discloses a 1, 2-dioxetane compound where, T is a stabilizing group (adamantly). The adamantyl group, spiro-bound, can be substituted at any bridge

head carbon, to affect chemiluminescent properties. The remaining carbon of the dioxetane ring bears a OR substituent, wherein R is generally an alkyl or cycloalkyl, although it may be a further aryl group. Preferred embodiments include substituted alkyls, with the substituent including halogenated groups, such as polyhaloalkyl substituents. The remaining valence is occupied by an aryl moiety, preferably phenyl or naphthyl. If naphthyl, particular substitution profiles on the naphthyl ring are preferred. The aryl ring bears at least one substituent, X. In commercially developed dioxetanes, this is an enzyme-cleavable group. For instance, many assays employ an exogenous enzyme, such as alkaline phosphatase, to ensure reliability of the assay. The enzyme is typically conjugated to a binding ligand, either an antibody, a nucleic acid fragment, or similar binding pair member, which will bind to the target substance to be detected. Where the conjugated enzyme is alkaline phosphatase, the enzyme-cleavable group X will be a phosphate. The aryl ring may also bear a substituent Y, which is selected to be either electron donating, or electron withdrawing. Preferred groups include chlorine, alkoxy and heteroaryl, although other groups may be employed. These substitutions further effect chemiluminescent properties, and reaction kinetics.

Uniformly, these dioxetanes are disclosed as useful enzyme substrates, that is, the binding pair member conjugated to an enzyme is allowed to bind to the target analyte, and after washing to remove unbound material, the dioxetane is added. In the presence of the conjugated enzyme, the protective group is cleaved, leading to decomposition of the dioxetane, and light emission. The thermal stability of the dioxetanes is superior to that of radioisotopes, fluorophores and other available

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chemiluminescent systems. Because biological assay conditions generally employ an aqueous media, water solubility, an important criteria, was met by use of the dioxetane substrates, which proved easy to use in both qualitative and quantitative determinations, in solutions, and in blotting assays. (col.2)

4. Claim 295-296 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The references in the PTO-1449, were lined through because they were not provided by applicants or they were missing a publication date.


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3 September 2006



JEZIA RILEY
PRIMARY EXAMINER